

US EPA ARCHIVE DOCUMENT

## **Risk Assessment and Risk Management Process**

### **Background.**

EPA is currently refining its processes for developing pesticide tolerance reassessment and reregistration decisions and documents. Under FQPA, cumulative risk assessment methodologies must now be incorporated into the risk assessment process, and risk management must now include a process for making tolerance and reregistration decision on not just a single chemical active ingredient, but on all pesticides that share a common mechanism of toxicity. The major goals of EPA's refined process must include achieving tolerance reassessment under FQPA's new requirements and FIFRA reregistration in the most efficient way possible while ensuring the use of sound science and transparency.

### **Risk Assessment and Risk Management Process Chart.**

The Agency shared with the TRAC its preliminary thinking on refined risk assessment and management processes. Several possible options with a range of elements were shared with TRAC for the purposes of generating discussion, and were in no way intended to represent the full range of options, or to limit the Agency or TRAC in anyway. The thoughtful consideration by TRAC has helped the Agency identify the topics and issues that are important to stakeholders, and has contributed to the drafting of a viable preliminary process. The attached chart (Staff Paper #22, TRAC 7/28/98) presents the draft tolerance reassessment/reregistration process that reflects the discussions and comments of Workgroup 2 and the full TRAC.

The chart displays the two major components, risk assessment and risk management, as parallel processes proceeding from left to right. The reason for displaying the two major components in parallel is to clearly communicate that this is a parallel, not a sequential process. The development of certain risk assessment tools and methodologies (for example, the methodology for conducting the cumulative risk assessment) will continue at the same time as risk management activities and actions are underway. In addition, the chart shows risk management is divided into FQPA tolerance reassessment and FIFRA reregistration. This highlights the fact that both tolerance reassessment and reregistration will be accomplished in the process.

The chart's parallel activity flow begins with the completion of individual chemical risk assessments and the initiation of FIFRA and FQPA risk management actions. Once the cumulative risk assessment methodology is available for use, the initial assessment is completed and major dietary risk drivers are identified. Risk management would be initiated for the major risk contributors identified during the cumulative assessment. In the mean time, implementation and transition of individual risk management decisions can continue (e.g., tolerance reassessments, registration modification or cancellations, tolerance revocations, etc.). The final

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cumulative assessment would then be completed for the remaining uses and tolerances, and the final risk management decisions made. Implementation and transition would be accomplished.

**TRAC Discussion.**

TRAC Workgroup 2 focused on possible elements of a new tolerance reassessment/reregistration process and options for the progression of this process. Much of the discussions focused on 2 issues: 1) the use of available and reliable data in the risk assessments, and 2) that the initial focus on taking early risk management action should not delay the initiation of the cumulative risk assessment. On the first topic, the TRAC discussed the need for using available and reliable data and methodologies in order to make sound risk assessment conclusions, while balancing the need to proceed with accomplishing FQPA's goals in a timely manner. Residential, drinking water, and cumulative risk assessment methodologies are under development. Interim methodologies can be used in most cases in the early part of the process to achieve appropriate risk mitigation.

On the second topic, the TRAC discussed the timing of the initiation of the cumulative assessment relative to ongoing risk management/mitigation activities on individual chemicals. Individual chemical risk management/mitigation can be started before the cumulative risk assessment is initiated, and continue and/or be completed once the cumulative assessment is underway (e.g., implementation of label changes, revocation actions, and other similar actions). A concern was raised that the initiation and completion of the cumulative risk assessment may be delayed by ongoing risk management activities. During the July 27, 1998 TRAC Workgroup 2 meeting, the workgroup drafted the following "consensus statement" that emphasizes their desire that risk assessment, including cumulative, and risk management not be a sequential process, rather that they continue in parallel. The Workgroup's consensus statement is as follows:

"Risk assessment on individual chemicals should proceed at the highest level of refinement consistent with available, reliable data. Individual risk mitigation (management) should begin and continue parallel to cumulative assessment and related cumulative risk management. This parallel process should continue until the process for cumulative risk assessment and risk management makes individual risk management activities inappropriate, invalid, or redundant. Nothing in the parallel process should delay moving to and through cumulative risk assessment and risk management."

**Next Steps.**

The Agency will proceed with tolerance reassessment and reregistration for the organophosphates consistent with the consensus process.